

Lafayette Range of Motion Inclinometer User Instructions



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Features

- Designed for high inter and intra instrument reproducibility
- Range of motion in three axis: left to right (L/R), front to back (F/B), and rotation (ROT)
- Data storage for up to 250 tests in on-board memory
- Storage of data on button press
- Measurement range 0-360 degrees
- Tone to indicate start and stop
- Microprocessor controlled
- Built-in stored data browsing capability
- Easy to read graphical LCD display
- Automatic shut off after 5 minutes of inactivity
- Battery indicator on LCD display
- Interactive menus allowing users to select device options
- Battery powered: (1) rechargeable lithium-ion battery

Specifications

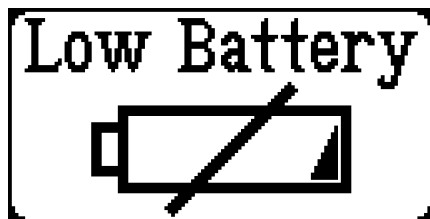
- Size: 4.61" x 3.27" x 0.97" (11.7cm x 8.3cm x 2.46cm)
- Weight: 121.4 g
- Range: 0-360 degrees
- Accuracy: $\pm 1\%$ over full range in vertical axis, $\pm 2\%$ over full range in horizontal axis
- Resolution: 0.1 degrees
- Battery Life: 10 hrs powered on, 30 minutes after low battery condition
- Battery Capacity: 900 - 1200 mAh Lithium Ion Rechargeable Battery
- Charge Time: 80% charge => 1 hour / Full charge => 3 hours
- Data Storage Capacity: 250 tests
- 50 ms sample rate

Precautions

- Upon initial receipt of ROMI, charge device for a minimum of 2 hours.
- When performing repeated tests, inconsistent placement of the ROMI will adversely affect scores.
- Extreme temperature, especially heat, may affect the values obtained.
- Large magnetic fields could affect the calibration or readings
- Care should be taken not to drop the ROMI.
- The plane of motion should be consistent and relative to the device
- This device uses a Lithium-Ion battery as a power source. It is recommended that the battery be charged at least once every six months. Failure to periodically charge the battery may result in battery damage or device malfunction.

Charging

The low battery indicator screen is shown when the battery needs to be charged. The screen will be displayed and then the system will power off. This screen will be displayed when the power button is pressed until the unit is recharged via the USB-C connector. The device should take about one (1) hour to charge 80% of the capacity, or about three (3) hours for a full charge.

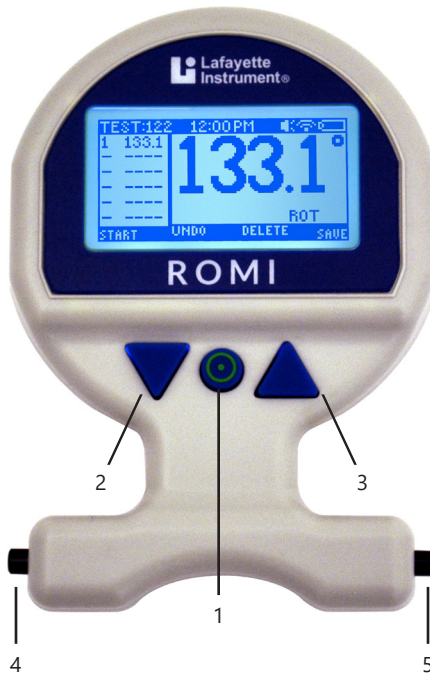


Lafayette Range of Motion Inclinator

Function Buttons

The ROMI has five function buttons that control the menus and allow the selection of options and settings.

- 1. POWER/MENU/SELECT Button:** The Round MENU/SELECT button is located on the bottom middle of the ROMI. This is the button used to power on the device. Holding the MENU/SELECT button for 5 seconds will power off the unit. It is placed for easy access regardless of right or left hand operation. The MENU/SELECT allows you to enter into the Menu screen and select various options within it.
- 2, 3. NAVIGATION Buttons:** While on the Test screen the NAVIGATION buttons are used to undo a trial or delete a test. While in the Menu screen, the NAVIGATION buttons are used to navigate the various menu screens.
- 4, 5. BASE buttons:** On the Test screen the BASE buttons are used to START/STOP tests and SAVE results when applicable. On the menu screen these buttons are used to return back one screen, BACK, or return to the Test screen, TEST. These buttons can be flipped for a specific dexterity by changing the button orientation in the OPTIONS menu. Double-click to start/restart a test.

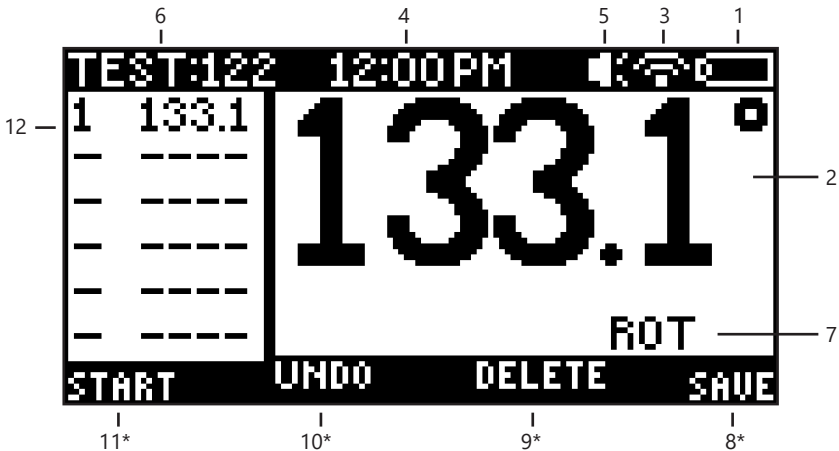


Screens

Test Screen

The Main Measurement Screen shows all measurement information that is being captured. This screen is shown whenever a measurement is in progress.

1. Battery Indicator: Indicates the remaining capacity in the charge of the battery.
2. Angle Display: Displays the current angle read during a test or the last trial while not testing.
3. Wireless Communication Indicator: This character indicates when the wireless is enabled.
4. Time Display: This time is displayed and can be set manually or synced with a PC in the Options Menu.
5. Sound Indicator: Indicates whether beeper is on or off for the current test.
6. Test Number: Displays the test number while a test is being displayed.
7. Axis of Rotation: Displays the axis of the current test relative to the device.
 - ROT: Rotation around the device
 - F/B: Front to back orientation
 - L/R: Left to right orientation
8. *SAVE: In this example, represents the label for the right BASE button. Save will save the current test.
9. *DELETE: In this example, represents the label for the UP arrow button. Delete will remove all current trials without saving.
10. *UNDO: In this example, represents the label for the DOWN arrow button. Undo will remove the last trial without saving.
11. *START/STOP: In this example, represents the label for the left BASE button. Start will start a new trial. Stop will stop the current trial and add it to the trial list.
12. Trial List: This window displays the trial number and the angle the trial was ended on.



* Indicates button mapping for option will change depending on chosen button orientation - set in OPTIONS menu

Lafayette Range of Motion Inclinator

Dual Setup Menu Screen

The Dual Setup menu allows users to connect two (2) devices together for dual inclinometry. Once selected from the main menu, there are two options to select from. CONNECT TO LAST DEVICE will look for the last companion device connected and will attempt to connect to it without scanning. The companion device will need to be powered on and wireless option will need to be set to ON. SCAN FOR NEW DEVICE will scan for any devices nearby. This could take 20-30 seconds.

Once the main device connects to the companion unit, the screen on the companion will display "Connected To Peer Device".

Once connected, navigate back the test menu on the main device and run normal tests now using both the main and companion units. The main device dictates the orientation of the trial. When beginning a test, the main device and companion unit should start in the same orientation and plane. The main device will automatically calculate the combined angle and display it on the screen.

To disconnect the devices, select the Dual Setup icon in the main menu. Once the devices are disconnected from each other, they can be used individually for single inclinometry.



Saved Data Menu Screen

The Saved Data menu allows users to manage tests that have been saved in the internal memory.



12:00 PM

Select to Open

TEST	TRIALS	MAX	DATE
▶ 10	6	40.0°	04 JAN 22 ▲
09	1	28.4°	02 JAN 22
08	6	27.5°	01 JAN 22
07	6	21.1°	01 JAN 22 ▼

TEST:1 12:00 PM

TRIAL	ANGLE	ORIENT.	AUG: 119.6°
1	119.2°	L/R	MIN: 118.9°
2	120.5°	L/R	MAX: 120.5°
3	119.1°	L/R	
4	120.2°	L/R	
5	118.9°	L/R	

12:00 PM

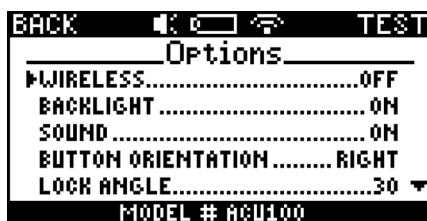
Select to Delete

TEST	TRIALS	MAX	DATE
▶ 10	6	40.0°	04 JAN 22 ▲
09	1	28.4°	02 JAN 22
08	6	27.5°	01 JAN 22
07	6	21.1°	01 JAN 22 ▼

Options Menu Screen

The Options menu allows user to customize the setup of their unit.

- WIRELESS: Toggles on/off the module for wireless connection.
- BACKLIGHT: Toggles unit's backlight on/off.
- SOUND: Toggles unit's sound on/off.
- BUTTON ORIENTATION: Switches the functionality of the base buttons, allowing for use in either hand.
- LOCK ANGLE: Changes the angle that locks the device in its axis.
- DATE: Updates the ROMI system date.
- TIME: Updates the ROMI system time.



Lafayette Range of Motion Inclinomometer

Information Menu Screen

The Information menu provides a contact email and various information about the ROMI.



Sensor Calibration

The sensor performs self-calibration, but the device also monitors the current calibration status both when the test window opens and at the beginning of a trial. The calibration window is displayed when the calibration status shows it is not fully calibrated. The window displays three letters for each sensor followed by the number representing the calibration status (0-3) as shown here:



Accelerometer (A)

This sensor can be calibrated by placing the device in six (6) different stable positions for a few seconds. For complete calibration, there should be slow movement between at least two (2) of the positions and there must be at least one (1) position perpendicular to the x, y, and z axis.

Gyroscope (G)

This sensor can be calibrated by placing the device in a stable position for a few seconds.

Magnetometer (M)

This sensor can be calibrated by making random movements until the until sensor reads fully calibrated (sensor calibration status is 3).

Calibration Values

- 0: Sensor is not calibrated
- 1: Sensor is partially calibrated
- 2: Sensor is partially calibrated
- 3: Sensor is fully calibrated

Sample Exercises

Sample: Storing Multiple Data Readings

1. Hold inclinometer in natural, neutral position
2. Flex your hand. When maximum flex has been reach press the left base button.
3. Repeat steps 1-2 to store up to six measurement readings.
4. The Saved Data can be viewed by pressing the POWER/MENU/SELECT button

Sample: Cervical Lateral Bending - Single Inclinometer

Prepare Inclinometer

1. Power on device by pressing the POWER/MENU/SELECT button.
2. Position individual's head in a neutral position.
3. Place device over calvarium.



Neutral

Take Measurements

1. Press the left BASE button* to begin the test.
2. Ask individual to bend their head to the left.
3. When individual reaches maximum range of motion, press the left BASE button* to store the maximum left cervical later bending angle.
4. Ask individual to return to neutral position. Double-click BASE button to start/restart test.
5. Repeat measurement steps 1-4 three to six times to achieve validity criteria of +/- 5 degrees or 10%.
6. Once all measurements have been completed, press the right BASE button* to store the entire test into memory
7. Follow steps 1-6 to measure right cervical lateral bending.



Left Lateral

Sample: View Data

1. To recall stored data, press the POWER/MENU/SELECT button to display the Settings menu.
2. Press the UP arrow button to highlight the Saved Data icon and press the POWER/MENU/SELECT button again to display the stored data options, then press POWER/MENU/SELECT to choose OPEN SAVED TESTS.



Right Lateral

* Indicates button mapping for action will change depending on chosen button orientation - set in OPTIONS menu

Resets

To restore to factory defaults, press POWER/MENU/SELECT and navigate to the Information screen. Press and hold POWER/MENU/SELECT then press the left BASE button consecutively until screen reads "Factory reset will delete all tests and all settings". Follow the prompts on screen until the screen reads "Factory reset complete!".

Hard Reset: If the inclinometer freezes press DOWN arrow and the UP arrow until the unit powers off and back on.

Firmware Updates

Lafayette Instrument periodically updates the firmware for select products. Visit our website to download our Firmware Updater software. The ROMI can be updated by plugging in the USB charger into your computer and downloading the current version of the firmware via the Firmware Updater.

Inclinometer Cleaning

Hard surfaces can be cleaned with a bleach-free sanitizing wipe. Alcohol wipes may also be used. Cloth or foam surfaces can be cleaned with anti-bacterial soap and water and allowed to air dry. Care must be taken to not allow water to penetrate the enclosure as damage to the circuit may occur.

Disclaimer: These cleaning instructions for Lafayette Instrument products are a recommendation of compatible cleaning materials only. Product end users are responsible for instituting an appropriate cleaning regimen utilizing best practices and techniques. Lafayette Instrument assumes no responsibility for the cleanliness or sanitation of the products after initial use nor makes any claim that the use of the recommended cleaning materials mitigates all risk of potential cross infection.

FCC Compliance Statement

Contains FCC ID: A8TBM78ABCDEFGH

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The FCC ID for the ROMI is available via the device menu by selecting **MENU > INFORMATION**.

Lafayette Range of Motion Inclinometer

Symbol Glossary

The following glossary describes the symbols included on the device label. Some symbols may not apply to this device.



Manufacturer

Indicates the medical device manufacturer
ISO 15223-1:2016 Ref. 5.1.1



Authorized Representative

Indicates authorized representative in the EU
ISO 15223-1:2016 Ref. 5.1.2



Date of Manufacture

Indicates date when device was manufactured
ISO 15223-1:2016 Ref. 5.1.3



Use by Date

Indicates date after which the device is not to be used
ISO 15223-1:2016 Ref. 5.1.4



Batch Code

Identifies the manufacturer's lot or batch code
ISO 15223-1:2016 Ref. 5.1.5



Catalog Number

Indicates the manufacturer's part number
ISO 15223-1:2016 Ref. 5.1.6



Serial Number

Identifies the manufacturer's serial number
ISO 15223-1:2016 Ref. 5.1.7



Sterile

Indicates that a device has been subject to sterilization
ISO 15223-1:2016 Ref. 5.2.1



Do not use if package is damaged

Indicates device should not be used if opened
ISO 15223-1:2016 Ref. 5.2.8



Non-Sterile

Indicates a device has not been subject to sterilization
ISO 15223-1:2016 Ref. 5.2.7



Fragile, handle with care

Indicates device that needs careful handling
ISO 15223-1:2016 Ref. 5.3.1



Keep away from sunlight

Indicates a device needs protection from sunlight
ISO 15223-1:2016 Ref. 5.3.2



Temperature limit

Indicates upper and lower temperature limits
ISO 15223-1:2016 Ref. 5.3.7



Keep dry

Indicates device should be protected from moisture
ISO 15223-1:2016 Ref. 5.3.4



Do not reuse

Indicates a single use device
ISO 15223-1:2016 Ref. 5.4.2



Consult Instructions for use

Prompts the user to consult the user manual
ISO 15223-1:2016 Ref. 5.4.3



Contains latex

Indicates the presence of natural rubber latex
ISO 15223-1:2016 Ref. 5.4.5



Caution

Indicates the need to review cautionary information
ISO 15223-1:2016 Ref. 5.4.4



Humidity Limitation

Indicates the upper and lower limits of humidity
ISO 15223-1:2016 Ref. 5.3.8



CE Mark

Product is certified for sale in the EU
Regulation (EC) No. 765/2008 Annex II



Made in the USA

Device was manufactured in the USA
No Standard Applicable



Medical Device

Enclosed equipment is classified as a medical device
No Standard Applicable

Terms and Conditions

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Fax: +44 1509 817701

Email: eusales@lafayetteinstrument.com

Phone, Fax, Email or Mail-in Orders

All orders need to be accompanied by a hard copy of your purchase order. All orders must include the following information:

- Quantity
- Part Number
- Description
- Your purchase order number or method of pre-payment
- Your tax status (include tax-exempt numbers)
- Shipping address for this order
- Billing address for the invoice we'll mail when this order is shipped
- Signature and typed name of person authorized to order these products
- Your telephone number
- Your email address
- Your FAX number

Domestic Terms

There is a \$50 minimum order. Open accounts can be extended to most recognized businesses. Net amount due 30 days from the date of shipment unless otherwise specified by us. Enclose payment with the order, charge with VISA, MasterCard, American Express, or pay COD. We must have a hard copy of your purchase order by mail, E-mail or fax. Students, individuals and private companies may call for a credit application.

International Payment Information

There is a \$50 minimum order. Payment must be made in advance by: draft drawn on a major US bank; wire transfers to our account; charge with VISA, MasterCard, American Express, or confirmed irrevocable letter of credit. Proforma invoices will be provided upon request.

Exports

If ordering instrumentation for use outside the USA, please specify the country of ultimate destination, as well as the power requirements (110V/60Hz or 220V/50Hz). Some model numbers for 220V/50Hz will have a "C" suffix.

Quotations

Quotations are supplied upon request. Written quotations will include the price of goods, cost of shipping and handling, if requested, and estimated delivery time frame. Quotations are good for 30 days, unless otherwise noted. Following that time, prices are subject to change and will be quoted at your request.

Cancellations

Orders for custom products, custom assemblies or instruments built to customer specifications will be subject to a cancellation penalty of 100%. Payment for up to 100% of the invoice value of custom products may be required in advance. Cancellation for a standard Lafayette Instrument manufactured product once the product has been shipped will normally be assessed a charge of 25% of the invoice value, plus shipping charges. Resell items, like custom products, will be subject to a cancellation penalty of 100%.

Exchanges and Refunds

Please see the cancellation penalty as described above. No item may be returned without prior authorization of Lafayette Instrument Company and a completed Return Form. A copy of the Return Form or your assigned Return # (you will receive this via email after submitting the form) must be included with the returned goods. The merchandise should be packed well and fully insured. Unopened merchandise may be returned prepaid within thirty (30) days after receipt of the item and in the original shipping carton. Collect shipments will not be accepted. Returned products must be in saleable condition, and credit is subject to inspection of the merchandise.

Repairs

Instrumentation may not be returned without prior authorization by Lafayette Instrument Company and a completed Return Form. When you complete the Form, or call Lafayette Instrument, you will receive a Return #. Your Return # number will be good for 30 days. Address the shipment to:

Lafayette Instrument Company
3700 Sagamore Parkway North
Lafayette, IN 47904, USA.

Shipments cannot be received at the LIC PO Box. Items should be packed well, insured for full value, and returned along with a copy of the Return Form or the Return #. An estimate of repair will be given prior to completion ONLY if requested in an enclosed cover letter. We must have a completed purchase order by mail or fax, or repair work cannot commence for non-warranty repairs.

Damaged Goods

Damaged instrumentation should not be returned to Lafayette Instrument prior to a thorough inspection. If a shipment arrives damaged, note damage on delivery bill and have the driver sign it to acknowledge the damage. Contact the delivery service, and they will file an insurance claim. If damage is not detected at the time of delivery, contact the carrier/shipper and request an inspection within 10 days of the original delivery. Please call the Lafayette Instrument Customer Service Department for repair or replacement of the damaged merchandise.

Limited Warranty

Lafayette Instrument Company warrants equipment manufactured by the company to be free of defects in material and workmanship for a period of one year from the date of shipment, except as provided hereinafter. The original manufacturer's warranty will be honored by Lafayette Instrument for items not manufactured by Lafayette Instrument Company, i.e. resell items. This assumes normal usage under commonly accepted operating parameters and excludes consumable products.

Warranty period for repairs or used instrumentation purchased from Lafayette Instrument is 90 days. Lafayette Instrument Company agrees either to repair or replace, at its sole option and free of part charges to the customer, instrumentation which, under proper and normal conditions of use, proves to be defective within the warranty period. Warranty for any parts of such repaired or replaced instrumentation shall be covered under the same limited warranty and shall have a warranty period of 90 days from the date of shipment or the remainder of the original warranty period whichever is greater. This warranty and remedy are given expressly and in lieu of all other warranties, expressed or implied, of merchantability or fitness for a particular purpose and constitutes the only warranty made by Lafayette Instrument Company.

Lafayette Instrument Company neither assumes nor authorizes any person to assume for it any other liability in connection with the sale, installation, service or use of its instrumentation. Lafayette Instrument Company shall have no liability whatsoever for special, consequential, or punitive damages of any kind from any cause arising out of the sale, installation, service or use of its instrumentation.

All products manufactured by Lafayette Instrument Company are tested and inspected prior to shipment. Upon prompt notification by the Customer, Lafayette Instrument Company will correct any defect in warranted equipment of its manufacture either, at its option, by return of the item to the factory, or shipment of a repaired or replacement part. Lafayette Instrument Company will not be obliged, however, to replace or repair any piece of equipment, which has been abused, improperly installed, altered, damaged, or repaired by others. Defects in equipment do not include decomposition, wear, or damage by chemical action or corrosion, or damage incurred during shipment.

Limited Obligations Covered by this Warranty

1. In the case of instruments not of Lafayette Instrument Company manufacture, the original manufacturer's warranty applies.
2. Shipping charges under warranty are covered only in one direction. The customer is responsible for shipping charges to the factory if return of the part is required.
3. This warranty does not cover damage to components due to improper installation by the customer.
4. Consumable and/or expendable items, including but not limited to electrodes, lights, batteries, fuses, O-rings, gaskets, and tubing, are excluded from warranty.
7. Failure by the customer to perform normal and reasonable maintenance on instruments will void warranty claims.
8. If the original invoice for the instrument is issued to a company that is not the company of the end user, and not an authorized Lafayette Instrument Company distributor, then all requests for warranty must be processed through the company that sold the product to the end user, and not directly to Lafayette Instrument Company.

Export License

The U.S. Department of Commerce requires an export license for any polygraph system shipment with an ULTIMATE destination other than: Australia, Japan, New Zealand or any NATO Member Countries. It is against U.S. law to ship a Polygraph system to any other country without an export license. If the ultimate destination is not one of the above listed countries, contact us for the required license application forms.